Remarks:

1. Claims 9-12, 23-25, and 32 are pending.

2. Claims 12 and 23 are amended. Claim 12 is amended for clarification. Claim 23 is amended in section (d) such that the subject isolated or purified polynucleotide encodes a functional neuromedin U receptor with a naturally occurring sequence. Support for this amendment is found in the specification, for example, for "naturally occurring" at page 19, lines 28-31, and for "functional" at page 77, lines 3-4. No new matter is added by amendment.

3. Claims 9-12, 23-25, and 32 stand rejected, under 35 U.S.C. § 101, for lack of utility. Claims 9-12, 23-25, and 32 stand rejected, under 35 U.S.C. § 112, first paragraph, for lack of enablement. Claims 9-12 and 23 stand rejected, under 35 U.S.C. § 112, first paragraph, for lack of written description. Claim 12 stands rejected, under 35 U.S.C. § 102, for lack of novelty.

4. Utility - 35 U.S.C. § 101

All claims stand rejected for lack of utility based upon the Examiner's argument that the specification fails to establish a specific and substantial utility for the claimed polynucleotide sequences, and that this purported deficiency is not cured by well-established utility that is substantial, specific, and credible. The Examiner argues (see page 4 of the February 11, 2003 Office Action) that "... the mere assertion that the polynucleotides (sic) sequences of the present invention have utility as encoding neuromedin U receptors that bind neuromedin U is not sufficient to provide the knowledge of the biological and physiological functions and a specific and substantial utility or a well-established utility. No art of record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the claimed invention." Applicants traverse this rejection.

As an initial point, Applicants note that the specification demonstrates that the claimed polynucleotide sequences have utility as neuromedin U receptors that, for example, specifically respond to neuromedin U in transfected host cells (see specification, at page 77, lines 3-5, and Figure 2). Therefore, Applicants dispute the Examiner's characterization that the specification "merely asserts" the utility of the claimed polynucleotide sequences. The claimed polynucleotides, expressed in transfected host cells, have a well-established utility that is specific and substantial because the host cells can be used for functional and binding studies to measure neuromedin U in a sample. One of ordinary skill in the art would have

recognized this utility as well-established at the time of filing, as demonstrated, for example, by references previously cited in the Information Disclosure Statement of March 19, 2001: Howard et al., Nature 406: 70-74, July 6, 2000 (hereinafter "Howard"), and Hosoya et al., J. Biol. Chem. 275: 29528-32, July 6, 2000 (hereinafter "Hosoya"). Both of these references report dose-dependent functional assays and competitive binding assays using host cells transfected with other neuromedin U receptors. These methods can readily be used, in a "real world context" to measure the neuromedin U content of a sample using cells transfected with and expressing the claimed polynucleotides.

The Howard and Hosoya references also discuss, in their Abstract and Introduction sections, respectively, the various significant biological activities of neuromedin U, further indicating the value of measuring this ligand in a biological sample and identifying compounds that modulate the activity of the receptor encoded by the claimed polynucleotides. These activities include inducing smooth muscle contractions, elevating blood pressure, inducing adrenocorticotropin and corticosterone release, altering ion transport in the gut, controlling local blood flow, and suppressing food intake. As the Examiner noted, Hosoya states in the Discussion section that the two neuromedin U receptors studied, TGR-1 and FM-3, have different "distributions and functions among tissues in vivo." However, the Hosoya discussion (page 29531, column 1) also states that "the receptors are closely related both structurally and functionally" and ties the different functions of the FM-3 and TGR-1 receptors only to their different expression patterns (page 29531, columns 1 and 2). The particular expression pattern of the neuromedin U receptor encoded by the claimed polynucleotides is provided in the specification (see page 74). Accordingly, there is no information in the Hosoya reference that rebuts the position that the claimed polynucleotides function as neuromedin U receptors in the relevant tissues disclosed in the specification. For all the above reasons and for the totality of evidence now of record, Applicants request reconsideration and withdrawal of the rejection for lack of utility.

5. Enablement - 35 U.S.C. § 112, first paragraph

All claims stand rejected for lack of enablement in view of the lack of utility rejection. For all of the reasons discussed above, Applicants request reconsideration and withdrawal of this rejection.

In addition, the Examiner rejects claims 9-12 and 23 for lack of enablement with respect to polynucleotides having at least 95% identity to disclosed sequences. In view of the current amendment to claim 23 (from which claims 9-12 currently depend), the Examiner's

argument, in the Office Action of November 2, 2001, that one skilled in the art would not be able to identify what substitutions and deletions could be made that would not produce deleterious effects to the overall activity and effectiveness of the polypeptide encoded by the claimed polynucleotides, is now rendered moot. As currently amended, such modifications to sequences encoding receptors with naturally occurring sequences are not relevant to the claim. Accordingly, Applicants respectfully request withdrawal of this rejection.

6. Written Description - 35 U.S.C. § 112, first paragraph

Claims 9-12 and 23 stand rejected for inadequate written description as related to polynucleotide sequences having at least 95 % identity to the disclosed sequences. In view of the claim 23 amendment incorporating the term "naturally occurring," Applicants assert that the claimed polynucleotides, as disclosed in the specification, provide definitive structural and functional description such that one skilled in the art could readily identify the polynucleotides encompassed by the claims and recognize that Applicants were in possession of the claimed genus. Accordingly, Applicants respectfully request withdrawal of this rejection.

7. Novelty - 35 U.S.C. § 102

Claim 12 has been rejected for lack of novelty. In view of the current claim amendment in a form related to that suggested by the Examiner, Applicants request reconsideration and withdrawal of this rejection.

8. In summary, Applicants submit that all claims are in condition for allowance and such action is respectfully requested.

Respectfully submitted,

Date: July 11th, 2003

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